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INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

(51) International Patent Classification 5 : A61B 17/22 — A1

(11) International Publication Number: WO 91/01689

(43) International Publication Date: 21 February 1991 (21.02.91)

(21) International Application Number: PCT/US90/04233

(22) International Filing Date: 27 July 1990 (27.07.90)

(30) Priority data:
386,215 28 July 1989 (28.07.89) US

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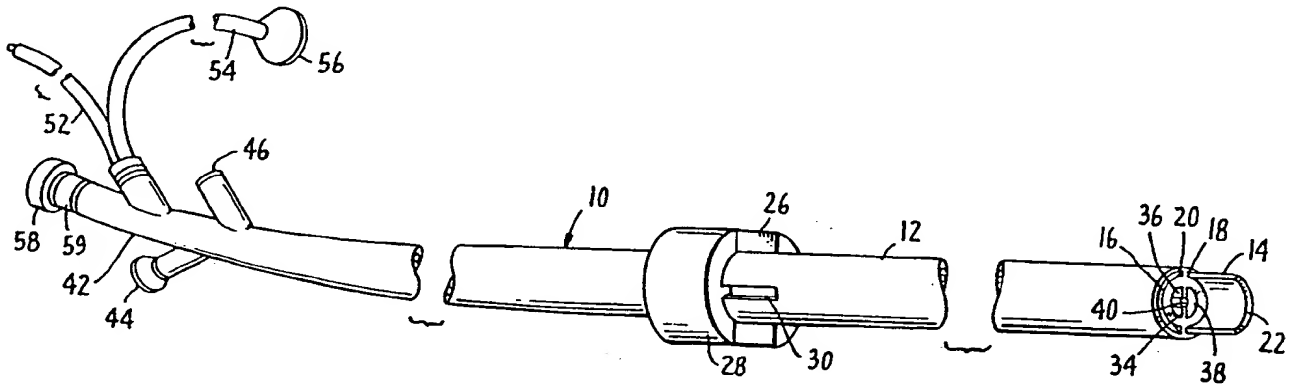
(81) Designated States: AT (European patent), AU, BE (European patent), CH (European patent), DE (European patent)*, DK (European patent), ES (European patent), FI, FR (European patent), GB (European patent), IT (European patent), JP, KR, LU (European patent), NL (European patent), NO, SE (European patent).

Published
With international search report.
Before the expiration of the time limit for amending the claims and to be republished in the event of the receipt of amendments.

(54) Title: VALVULOTOME CATHETER



(57) Abstract

A catheter-cutter for aorto-coronary bypass graft cutting of vein valves within a vein graft and for the in-situ bypass vein graft cutting of the valves within a vein includes at-least-one arcuate razor-sharp, tip-angle-edged cutting blade element (14) extending from the open distal end of the catheter (10), the at-least-one cutting blade element (14) being fixed or selectively extendable from the distal end of the catheter by optional control means (26) carried at the proximal port of the catheter, the at-least-one cutting blade element (14) being effective to cleanly excise and clearly cut a valve, the catheter optionally including a fiberoptic viewer (82) for observing the cutting process and optionally including a selectively inflatable balloon (50) about the catheter tube at its very distal end to accurately fix the position of the at-least-one cutting blade element and also to act as a buffer, if desired, during catheter insertion and manipulation while the catheter tube is being negotiated in a forward direction within the vein being modified.

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VALVULOTOME CATHETER

Background of the Invention

Field of the Invention

This invention relates to medical instrumentation and, more specifically, to such instrumentation as applied in the fields of cardiac surgery and peripheral vascular surgery.

Prior Art

Arterial reconstruction utilizing an autologous saphenous vein is widely used in the field of peripheral vascular surgery in the lower extremities and has become well established as the customary graft source for aorto-coronary bypass graft surgery.

In peripheral vascular surgery, in-situ bypass grafting has become more and more the operation of choice for bypassing from the suprageniculate to the infrageniculate arteries and re-establishing arterial blood flow. The autogenous saphenous vein is historically similar to an artery and is the standard to which all other grafts are compared.

The earliest experiences with venous autogenous grafts, although experimental at that time, were gained by Gluck in 1894, followed by Exner and Hopfner in 1903. In the United States, Julian, et al., Lord and Stone, Dale, et al., and Linton and Darling pioneered the wide use of an autologous vein in femoral-popliteal arterial reconstructive procedures. The concept of using the saphenous vein in-situ is attributed to Karl Hall, who in 1959 suggested that the saphenous vein

bypass might improve if the vein were left in place and the valves were rendered incompetent. He was the first, in 1962, to successfully report the use of the in-situ vein graft procedure as an arterial bypass. Further, the technique of in-situ bypass grafting was augmented by Leather and Karmody who used valve strippers to disrupt the grafted vein valves.

With the increasing experience worldwide, it was apparent that the crux of the in-situ vein graft was the method of removing the valvular obstructions to distal arterial flow. To achieve the in-situ disruption of the valves, various techniques have been used:

1. miniature scissors inserted through a venotomy proximal to the respective valve site to incise the valves;

2. thin incising vein-strippers passed through the vein in the distal to the proximal direction;

3. bullet-shaped metal strippers introduced in anterograde or retrograde directions, employing incising parts in different shapes;

4. long, thin-shaped valvulotomes with curved, hook-like incising tips which incise the valve leaflets upon pulling the device back through the valve;

5. double cylinder strippers having incising parts affecting the valves when such parts are pulled in a reverse direction; and

6. thin incision fingers extending from the open distal end of a catheter that is being pulled from the proximal part of the vein toward its distal portion by an accessory pulling instrument that has been secured to the catheter after being introduced through the distal part of the vein.

For coronary arteries autologous saphenous vein grafts have been widely used since 1967 in aorto-coronary bypass grafting procedures for symptomatic coronary artery disease treatment.

Autogenous reversed saphenous vein grafting has become routine for aorto-coronary bypass surgery. With this method the saphenous vein valves are left intact and the vein graft is reversed. The distal portion of the grafted vein (which becomes proximal in the graft) is usually larger in diameter than the replaced coronary artery, resulting in reduced blood flow velocity in the vein graft compared to that in the coronary artery. These grafts provide an early patency rate of 98%, a routine elective mortality rate of approximately 1%, and a myocardial infarction rate of approximately 3%. The patency rate of coronary vein grafts is approximately 85% by the end of the first year postoperative, and the attrition rate continues by approximately 2% per year for the next four to five years. Progressive stenosis continues, and the patency rate of coronary vein grafts at three years postoperative is approximately 70% and is approximately 60% at five years postoperative.

At ten years postoperative, atherosclerosis becomes the major cause of coronary vein graft failure.

The vein graft occlusion rate doubles at between five and ten years postoperative.

Performance of coronary reversed saphenous vein grafts relates, among other factors, to the intact valves which are implicated in graft failure. Studies suggest that valves do not open fully during reversed blood flow and cause a decrease in the graft blood flow rate at specific obstruction-related points. The undisrupted valves, non-collapsed against the wall of the grafted vein, may cause them to stay in the main blood stream and become a site of turbulence to laminar flow and an origin for thrombus formation under the cusps. This is especially true with the decreased blood flow rate in large diameter vein grafts and with poor run-off.

Thrombosis may lead in these cases to myocardial infarction or, later, to increased stenosis and occlusion. Laminar flow at the venous valves causes a reaction of the vein grafts similar to a spasm, suggesting that the valves may be predisposed to an increased stenosis rate and a rapid occlusion rate of the vein grafts.

Additional experience evidenced that when more than one valve site was present in the body of the saphenous vein graft, occlusion, thrombus formation, or accelerated progressive atherosclerosis seemed to occur in anatomic correlation to these valves. Good flow velocity is essential to the patency and integrity of coronary vein bypass grafts, while flow disturbance and decreased blood flow velocity are important influencing factors affecting their integrity as well as short-term and long-term patency. Bisection of vein valves

significantly increases the blood flow rate through the vein grafts.

Prior art devices, while rendering the saphenous veins relatively incompetent, did not remove the valves with the result that complications such as stenosis, occlusion and thrombus formation, as previously recited, occurred. In cardiac surgery the protocol of coronary reversed vein grafts is subject to review and reversion if improved instrumentation becomes available and is proved to be effective to enhance patency rate and integrity.

Therefore, it is an object of this invention to provide a medical instrument that will overcome the general problems recited hereinbefore.

It is a further object of this invention to provide an easily operated cutting catheter that will effectively cut and remove the valves in the saphenous veins used as grafts for bypass peripheral surgery and aorto-coronary bypass surgery.

Summary of the Invention

Apparatus is provided for cutting the bi-cuspid venous valves free from the wall of a vein to be used in bypass vein graft surgery. This end is achieved by a catheter-cutter which comprises a catheter having one or two arcuate (convex) tip-angle-edged, razor-sharp cutting blade elements positioned at its distal end tip. The catheter has one or two channel lumens. In its center, or in a laterally displaced position, is a separate, shielded fiberoptic channel to provide real-time imaging control of manipulation of the catheter, thereby obtaining manipulation of its cutting blade

elements and inspection of the results. The fiberoptic channel is fixed in its position, extends from the distal tip of the catheter through the catheter, and connects to an eyepiece at its proximal end, which eyepiece may be connected to a video camera and to a television monitor. The fiberoptic channel is positioned either fixed within a catheter support wall which forms two centered lumens of the catheter, or is fixed in a lateral position in the side wall of the catheter in the case wherein the catheter has only one centered lumen.

The two arcuate cutting blade elements, separated one from the other, can be manipulated independently or simultaneously, simultaneous manipulation resulting in an almost completely closed pattern of a circular cut-line. The two cutting blade elements move in their respective separated channels of related size and shape situated proximate to the outer periphery of the catheter, thus almost reaching in circular dimension the actual outer diameter of the catheter itself, thereby creating a minimal "dead space" between the circular cutting blade elements and the outer surface of the catheter, thus creating a spaced safety margin between the cutting blade elements and the inner surface of the vein wall. Inadvertent damage to the vein will not occur due to this special safety margin while negotiating the distal tip of the catheter forward with its fixed or extendable cutting blade elements. Each of the two arcuate cutting blade elements is angled at its tip-edge towards the center of the catheter (inward) providing a further safety margin to prevent damage to the intimal surface of the vein when negotiating the catheter and its extended cutting blade elements forward.

The arcuate cutting blade elements are movable forwards and backwards, are extendable out of the distal end of the catheter, and may be pulled back into the catheter to line up with its distal end. This mechanism is controlled by a two-part, two-color, split-ring control unit situated at the proximal part of the catheter and connected to the two arcuate cutting blade elements housed in their own separated channels so that pushing either of the semi-circular cutting blade elements of the split-ring control unit in the direction from the proximal part to the distal end will extend the respective arcuate cutting blade element from the distal end of the catheter. Reverse manipulation of the split-ring control unit will withdraw the cutting blade elements into the catheter and align the edges of the arcuate cutting blade elements with the distal end of the catheter. Since the split-ring control unit is made of two parts, the cutting blade elements can be manipulated independently or simultaneously.

The arcuate tip-angle-edged, razor-sharp cutting blade elements can be fixed at the distal end of the catheter to extend permanently from the distal end of the catheter to a predetermined length. In that case, the arcuate cutting blade elements may be contiguous (or continuous) to form a completely closed circular shape and may be considered to be one circular, razor-sharp, tip-angle-edged cutting blade element. The method of its use involves advancing the catheter-cutter with its fixed or selectively extendable cutting blade element or elements through the blood vessel being treated from its proximal portion towards its distal end, or, conversely, if inserted through the distal part of the vessel, from its distal portion to its proximal portion, in either case excising complete-

ly and effectively any valves or other obstructions within the vein graft.

A low-profile, inflatable-deflatable single segment or multi-segment balloon may be positioned at the distal tip of the catheter to serve two purposes. First, when inflated partially it covers completely the distal tip of the catheter, thus providing a beveled soft-tipped leading edge for the catheter when it is inserted into the vein or when it is negotiated forward within the lumen of the vein, thus preventing accidental vein-wall damage during the insertion or manipulation process, even in a tortuous vessel configuration. This structure is referred to herein as a "balloon-tipped" catheter. Second, in addition to the safety feature just described, when the catheter tip is precisely positioned the catheter may be fixed in this position by fully inflating the balloon tip.

The catheter can be disposable for single use and is made from flexible materials (i.e., polyethylene). The cutting blade elements, fixed or movable, can be made from metal.

At the proximal end of the catheter is a port connector that is connected to one of the center lumens (to the smaller one in the case of two unequal lumens) for irrigation of fluid that will be flushed through that specific central lumen out through the distal end tip of the catheter.

Through the other lumen a forceps-like biopsy device may be introduced to permit additional intraluminal manipulations. In the case wherein the catheter has only one central lumen, both of the

aforementioned activities may occur simultaneously through that single, wide lumen.

The distal part of the catheter may be constructed to permit rotation of the fixed cutting blade elements about the axis of the catheter-cutter at a low rotational velocity controlled from a small, hand-held battery-operated drive-motor unit.

In one aspect of the invention there is provided a valvulotome catheter comprising:

a tube having an outer wall and an inner wall radially spaced from said outer wall but supported therefrom to form at-least-one arcuate blade element chamber between said inner and outer walls; and

at-least-one arcuate blade element supported in said at-least-one arcuate blade element chamber and having a body portion and a cutting tip portion, said cutting tip portion being directed inwardly and terminating in a razor-sharp cutting edge.

In another aspect of the invention there is provided a valvulotome catheter comprising:

a tube having an outer wall having a distal end and a proximal portion;

a rotatable end portion supported at said distal end;

a pair of inwardly directed cutting blades each having a razor-sharp terminating end, and each fixedly supported in said rotatable end portion to rotate therewith;

a shaft extending from said rotatable end portion to said proximal portion of said catheter; and

rotating means mechanically coupled to said shaft at the proximal portion thereof to cause rotation thereof and of said rotatable end portion.

In yet another aspect of the invention there is provided a valvulotome catheter comprising:

a tube having a longitudinal axis, a radial axis and an outer wall; and

at least one arcuate blade element operatively supported by said outer wall, said at least one blade element having a body portion and a cutting tip portion, said cutting tip portion being directed radially inwardly and terminating in a razor-sharp cutting edge.

Brief Description of the Drawing

This invention can best be understood by taking the description which follows in conjunction with the drawing herein in which:

Fig. 1 is a mechanical schematic diagram of a valvulotome catheter according to the invention;

Fig. 1A is an enlarged view of a portion of the catheter of Fig. 1;

Figs. 2A, 2B and 2C are mechanical schematic diagrams showing alternative positioning of the elements of the invention;

Fig. 3 is a partial cross-sectional view of an alternative form of the invention;

Fig. 4 is a profile view of a cutting element for use in the invention;

Fig. 5 is a partial cross-sectional view of an alternative form of the invention;

Fig. 6 is a partial cross-sectional view of another embodiment of the invention; and

Figs. 7A and 7B are partial cross-sectional views of related portions of the device of Fig. 1.

Detailed Description of the Preferred Embodiments

In Figs. 1 and 1A, valvulotome catheter 10 includes tube 12 having an outer diameter of from 1.5 mm. to 6.5 mm., the outer diameter being chosen to fit the blood vessel in which the instrument is to be used.

Tube 12 carries a pair of arcuate razor-sharp cutting blade elements 14, 16 in channels 18, 20 located in the walls of tube 12. This can be seen more clearly in Figs. 7A and 7B. Blade elements 14, 16 terminate at their distal ends in razor-sharp cutting edges 22, 24, respectively.

Blade elements 14, 16 are withdrawable into and extendable from channels 18, 20, respectively and independently by way of ring-segment control elements 26, 28, respectively, which slide in slots 30, 32, respectively.

Central support element 34, as shown in Fig. 1, divides the inner space of tube 12 into two symmetrically disposed lumens 36, 38 which extend through tube 12. Support element 34 supports an optional fiberoptic bundle 40 which permits viewing of the operation and the effectiveness of cutting edges 22, 24 on blade elements 14, 16, respectively.

The proximal portion 42 of tube 12 includes flushing port connector 44 which communicates hydraulically with one of the lumens 36, 38 to permit flushing of valve debris from the area being cut by cutting edges 22, 24.

A connector 46, pneumatically coupled to an air passage 48 (Fig. 3) in the wall of tube 12, is provided for inflating a buffer balloon 50 (Fig. 3).

A fiberoptic element 52 is adapted for the application of light thereto to illuminate the area where the excising of valves is occurring. The cutting scene may be observed optically or recorded for later study by way of fiberoptic element 54 and eyepiece 56.

Port connector 58 has a hemostatic valve 59 associated therewith. It is coupled to one of the lumens 36, 38 for the introduction of biopsy-forceps-like catheters which may be required to extract excised valves or debris from the associated blood vessel.

Flushing port connector 44 is hydraulically coupled to the lumen not coupled to hemostatic valve port connector 58 for the introduction of irrigation fluid which may be necessary to flush excised valves and debris from the distal end of catheter 10 so as to assure a clear field of view when the fiberoptic bundle 40 is being used.

Turning to Figs. 2A, 2B and 2C, the positioning of support element 34 of tube 12 may vary. In Fig. 2A, support element 34 is centrally disposed, thus making fiberoptic bundle 40 coaxial with tube 12 and producing two symmetrically disposed and equal-sized lumens 36, 38. In Fig. 2B, the support element 34 is displaced,

the positioning of fiberoptic bundle 40 is also displaced from the center of tube 12 and two unequal lumens 60 and 62 are formed. In Fig. 2C there is a single lumen 64, and fiberoptic bundle 40 is off-axis in the wall of tube 12.

In the embodiment of Fig. 2C, the same procedure of manipulating biopsy-forceps-like catheters and irrigating and flushing procedures will occur through the single lumen. In this configuration flushing port connector 46 and hemostatic port connector 58 are coupled to the common lumen 64.

Turning to Fig. 3, at the distal end 70 of catheter 10 a low-profile balloon 50 is affixed. One purpose of balloon 50 is to hold fixed the position chosen by the surgeon for end 70. Another is to provide safety to the side walls of the vessel during catheter manipulation. Balloon 50 is inflated, by gas or liquid, through channel 72 which is carried in the wall of catheter 10 from the proximal port to the distal end of catheter 10. Balloon 50 may be segmented in which case multiple inflation channels must be provided, one for each segment. A multi-position control valve is provided at the proximal port of catheter 10 to selectively control whether either or both segments of balloon 50 are inflated. The selectable mode of inflation of balloon 50 permits a high degree of precision in the manipulation of catheter 10 and more accurate positioning thereof and of its cutting edges 22, 24.

Fig. 4 shows the profile of one of the razor-sharp, tip-angle-edged cutting blade elements in catheter 10. Of course, tip-angle-edged edges 22, 24

are highly polished and smooth on their external angled surfaces and sharpened to a razor-like edge.

In Fig. 5, tip-angle-edged cutting edges 74 and 76 are shown fixed, longitudinally, in the distal end 78 of tube 80. Valve cutting is achieved by manipulating tube 80 from the proximal to the distal end of tube 80. Conversely, tube 80 may be moved from the distal to the proximal end of tube 12. In either mode, tip-angle-edged cutting edges 74, 76 sever any valves from the inner wall of the vein. A fiberoptic bundle or channel 82 may be provided coaxially within tube 80.

In Fig. 6, the end portion 90 is rotatably supported from tube 12 by way of shaft 91 positioned by locating bearing 92 and support member 94. Shaft 91 terminates at its distal end in blade support member 96 which carries tip-angle-edged longitudinally-fixed cutting edges 98, 100. Rotation of shaft 91 at speeds of up to 50 r.p.m. by a small hand-held, battery operated drive motor at the proximal end of shaft 91 greatly enhances the cutting effectiveness of the catheter incorporating this feature.

While particular embodiments have been shown and described, it will be apparent to those skilled in the art that variations and modifications may be made therein without departing from the true spirit and scope of the invention. It is the purpose of the appended claims to cover all such variations and modifications.

I Claim:

1. A valvulotome catheter comprising:

a tube having an outer wall and an inner wall radially spaced from said outer wall but supported therefrom to form at-least-one arcuate blade element chamber between said inner and outer walls; and

at-least-one arcuate blade element supported in said at-least-one arcuate blade element chamber and having a body portion and a cutting tip portion, said cutting tip portion being directed inwardly and terminating in a razor-sharp cutting edge.

2. Apparatus according to Claim 1 in which said at-least-one arcuate blade element is fixed longitudinally in said catheter.

3. Apparatus according to Claim 1 in which said at-least-one arcuate blade element is longitudinally adjustable in position in said at-least-one blade element chamber.

4. Apparatus according to Claim 1 in which said at-least-one blade element chamber extends throughout the length of said catheter.

5. Apparatus according to Claim 3 in which a longitudinal adjustment element is connected to said at-least-one arcuate blade element, said outer tube having a slot therein and said longitudinal adjustment element extending through said slot.

6. Apparatus according to Claim 5 in which the number of arcuate blade elements and the number of longitudinal adjustment elements is two, one of said

longitudinal adjustment elements being connected to each of said arcuate blade elements.

7. Apparatus according to Claim 1 in which said outer wall and said inner wall of said catheter each have a distal end and a proximal portion and including, in addition, an inflatable-deflatable balloon carried on the distal end of said outer wall to form a balloon-tipped catheter; and

pneumatic coupling means coupled between said balloon and said proximal end of said outer wall for inflating and deflating said balloon.

8. Apparatus according to Claim 7 in which said balloon is a low-profile balloon.

9. Apparatus according to Claim 1 which includes, in addition, a fiberoptic channel carried within said catheter inner wall.

10. Apparatus according to Claim 9 in which said fiberoptic channel is positioned coaxially with respect to said inner wall.

11. Apparatus according to Claim 1 which includes, in addition, a divider element spanning the space between opposing points on the inner surface of said inner wall.

12. Apparatus according to Claim 11 in which said opposing points are diametrically opposed and said divider element forms two equal and symmetrical lumens within said inner wall.

13. Apparatus according to Claim 12 which includes, in addition, a fiberoptic channel supported centrally in said divider element.

14. Apparatus according to Claim 11 in which said opposing points are not diametrically opposed and said divider wall is off-axis forming two unequal lumens through said inner wall.

15. Apparatus according to Claim 1 in which the space between the inner surfaces forms a single lumen.

16. A valvulotome catheter comprising:

a tube having an outer wall having a distal end and a proximal portion;

a rotatable end portion supported at said distal end;

a pair of inwardly directed cutting blades each having a razor-sharp terminating end, and each fixedly supported in said rotatable end portion to rotate therewith;

a shaft extending from said rotatable end portion to said proximal portion of said catheter; and

rotating means mechanically coupled to said shaft at the proximal portion thereof to cause rotation thereof and of said rotatable end portion.

17. Apparatus according to Claim 12 including, in addition, flushing port means coupled to said lumens for flushing debris from said catheter.

18. Apparatus according to Claim 12 including, in addition, a homeostatic valve coupled to one of said lumens for the introduction of biopsy-forceps-like catheters.

19. Apparatus according to Claim 7 in which said balloon is segmented.

20. Apparatus according to Claim 1 in which said at-least-one arcuate blade element is continuous to form a complete single circular cutting edge and is fixed in longitudinal position within said catheter extending out from its cutting tip portion.

21. A valvulotome catheter comprising:

a tube having a longitudinal axis, a radial axis and an outer wall; and

at least one arcuate blade element operatively supported by said outer wall, said at least one blade element having a body portion and a cutting tip portion, said cutting tip portion being directed radially inwardly and terminating in a razor-sharp cutting edge.

22. Apparatus according to Claim 21 wherein said at-least-one arcuate blade element is fixed longitudinally with respect to said outer wall.

23. Apparatus as in Claim 21 wherein said at-least-one arcuate blade element comprises a pair of radially inwardly directed cutting blade elements each having a razor-sharp terminating end, said cutting blade elements being rotatable with respect to said outer wall.

24. Apparatus according to Claim 21 wherein said at-least-one arcuate blade element is continuous to form a circular cutting edge which is longitudinally fixed with respect to said outer wall.

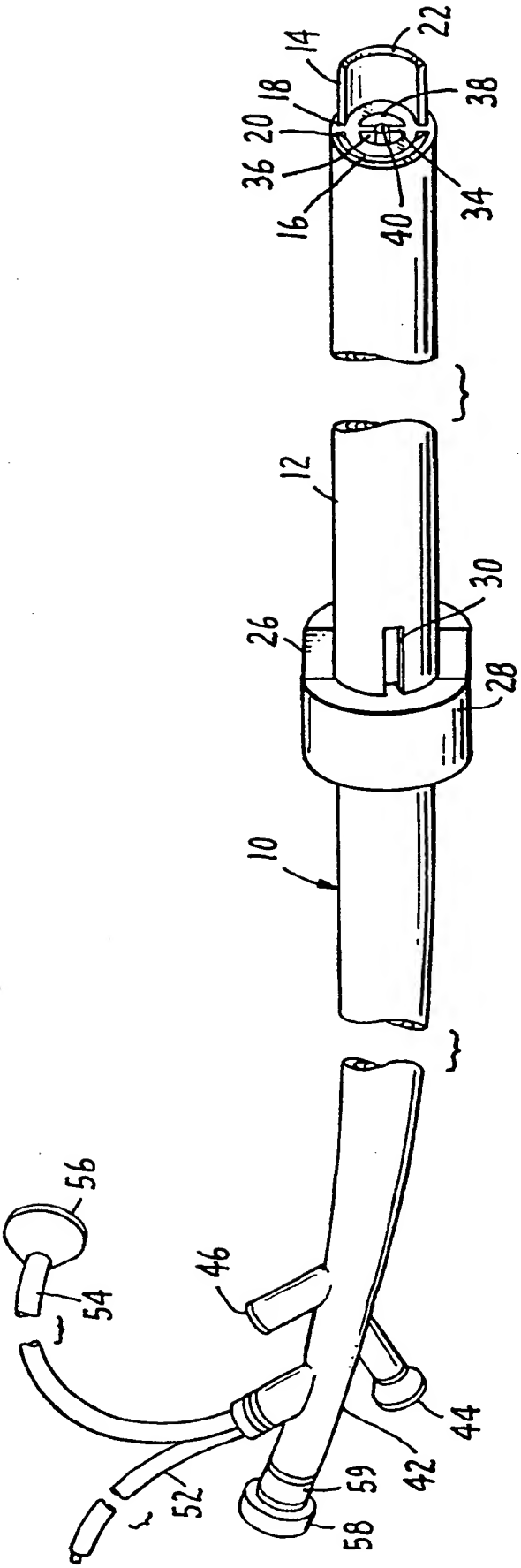

FIG. 1

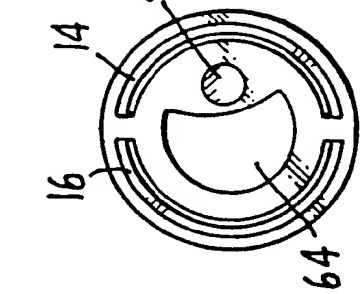

FIG. 2C

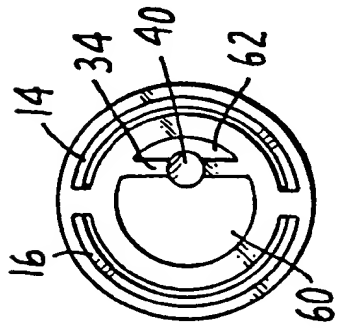

FIG. 2B

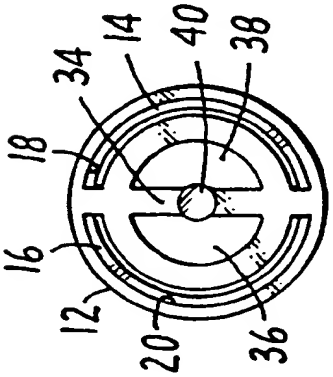

FIG. 2A

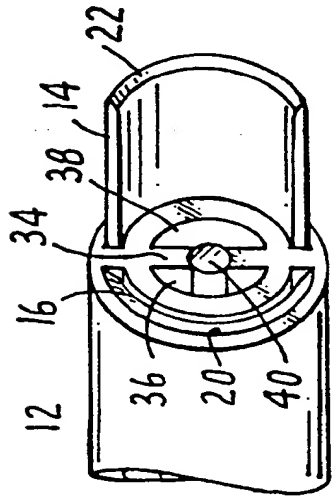

FIG. 1A.

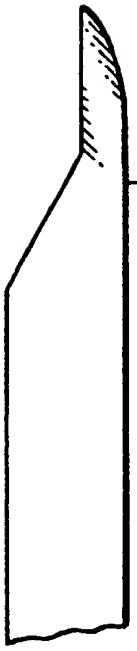

FIG. 4

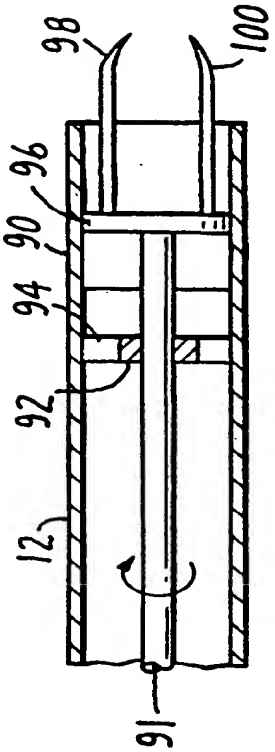

FIG. 6

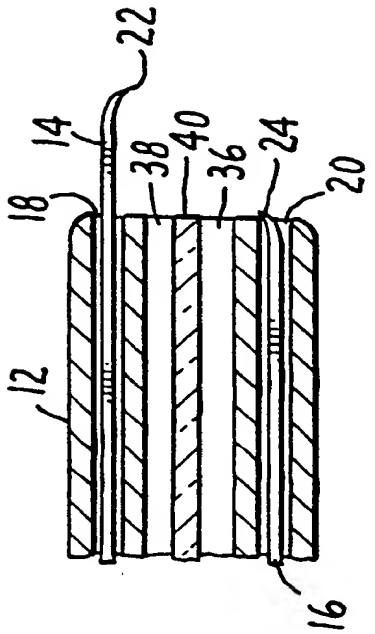

FIG. 2B

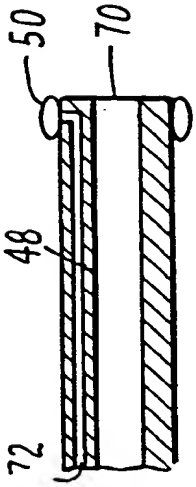

FIG. 3

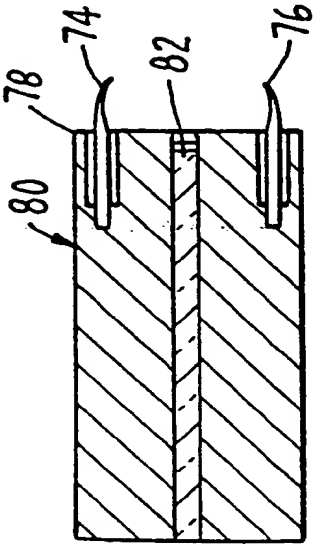

FIG. 5

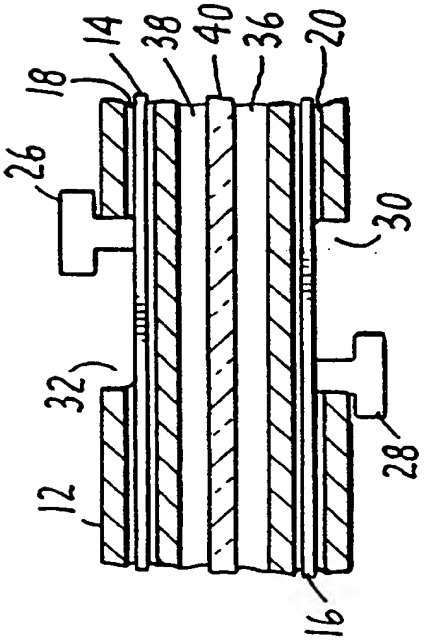

FIG. 7A

SUBSTITUTE SHEET

INTERNATIONAL SEARCH REPORT

International Application No PCT/US 90/04233

I. CLASSIFICATION OF SUBJECT MATTER (if several classification symbols apply, indicate all) 3

According to International Patent Classification (IPC) or to both National Classification and IPC

IPC (5): A61B 17/22
U.S.: 606/159

II. FIELDS SEARCHED

Minimum Documentation Searched 4

Classification System	Classification Symbols
U.S.	604/22, 128/4-6 227/19, DIG 1. 30/162,304, 305, 335 606/156, 159, 166, 170, 179

Documentation Searched other than Minimum Documentation to the Extent that such Documents are Included in the Fields Searched 5

III. DOCUMENTS CONSIDERED TO BE RELEVANT 14

Category *	Citation of Document, 16 with indication, where appropriate, of the relevant passages 17	Relevant to Claim No. 18
X	US, A, 3,837,345 (MATAR) 24 September 1974 See entire document	21
X	US, A, 4,427,014 (BEL ET AL) 24 January 1984 See entire document	1,3,4,9,10, 15, 19
Y	US, A, 4,784,636 (RYDELL) 15 November 1988 See entire document	7,8
X,P Y	US, A, 4,926,858 (GIFFARD, III ET AL) 22 May 1990 See entire document	1,3,4,15,19 7, 8

* Special categories of cited documents: 15

"A" document defining the general state of the art which is not considered to be of particular relevance

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"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

IV. CERTIFICATION

Date of the Actual Completion of the International Search 2	Date of Mailing of this International Search Report 2
23 October 1990	10 DEC 1990
International Searching Authority 1	Signature of Authorized Officer 20
ISA/US	WILLIAM W. LEWIS

Form PCT/ISA/210 (second sheet) (May 1986)